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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/881,736	06/18/2001	Michael Glotzer	0652.2260001/EKS/AES	8755
26111	7590	08/11/2005	EXAMINER	
STERNE, KESSLER, GOLDSTEIN & FOX PLLC 1100 NEW YORK AVENUE, N.W. WASHINGTON, DC 20005			LI, RUIXIANG	
			ART UNIT	PAPER NUMBER
			1646	

DATE MAILED: 08/11/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/881,736

Applicant(s)

GLOTZER ET AL.

Examiner

Ruixiang Li

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 23 May 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☐ Claim(s) 1-6, 12, 45, 46, 48-57, 59-64, and 67-77 is/are pending in the application.
- 4a) Of the above claim(s) 1-6, 12 and 74-77 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 45, 46, 48-57, 59-64, 67-73 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

Status of Application, Amendments, and/or Claims

Applicants' amendment filed on 05/23/2005 has been entered in full. Claims 1-6, 12, 45, 46, 48-57, 59-64, and 67-77 are pending. Claims 45, 46, 48-57, 59-64, 67-73 are under consideration.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office Action.

Withdrawn Objections and/or Rejections

The rejection of claim 45, 46, 51-64, and 68-73 under 35 U.S.C. 112, 2nd paragraph as being indefinite, as set forth at pages 4-6 of Paper No. 02172005 (mailed on 02/23/2005), has been withdrawn in view of amended and canceled claims.

The objection to claims 48-50 and 67 has been withdrawn.

Claim Rejections under 35 U.S.C. § 112, 1st Paragraph, Scope of Enablement

Claims 45, 46, 48-57, 59-64, and 67-73 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method for identifying a compound having the potential to inhibit cytokinesis employing a

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CYK-4 protein set forth in SEQ ID NO: 2, 4, or 6 does not reasonably provide enablement for a method for identifying a compound having the potential to inhibit cytokinesis employing any other CYK-4 proteins. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

The amended claims are still broad and encompass a screening method employing any CYK-4 proteins and its fragments. Claim 45 recites "a fragment of the CYK-4 protein comprising a GTPase activating protein domain". Claim 54 recites "a fragment of the CYK-4 protein comprises a domain that binds MKLP1 subfamily proteins". Claim 55 recites "a fragment of the MKLP1 protein subfamily member that comprises a domain that binds the CYK-4 protein or fragment of the CYK-4 protein". Claim 64 recites a fragment of the first CYK-4 protein and the second CYK-4 protein, each comprises a domain that mediates CYK-4 protein self-association. However, there is no specific structure of the domain is recited in the claims.

Claims 45, 54, and 64 recite variants of human CYK-4 (SEQ ID NO: 2) and murine CYK-4 (SEQ ID NO: 4) that are encoded by nucleic acids hybridizing under stringent conditions to a polynucleotide having a nucleotide sequence set forth in SEQ ID NO: 1 or SEQ ID NO: 3. Claims 48, 59, and 67 recite variants of human CYK-4 (SEQ ID NO: 2). The specification only provides a single species

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of CYK-4 for human CYK-4 of SEQ ID NO: 2 and murine CYK-4 of SEQ ID NO:

4. There is no sufficient guidance and/or working examples provided in the specification to make and use variants of the human CYK-4 and murine CYK-4 protein. The prior art at the time when the instant application was filed does not teach additional CYK-4 proteins that play critical roles in cytokinesis. Moreover, the state of the art is such that determining the specificity of hybridization is empirical by nature and the effect of mismatches is unpredictable, as taught by Wallace et al. (Methods Enzymol. 152:432-443, 1987) and Sambrook et al. (Molecular Cloning, A Laboratory Manual, 2nd Edition, 1989, Cold Spring Harbor Laboratory, Cold Spring Harbor, NY, page 11.47). It is well known in the art that hybridisation yields structurally related, but functionally different nucleic acids. In this regard, it is noted that there is no functional limitation for the variant encoded by nucleic acids that are produced by hybridization. Thus, it would take undue experimentation for one skilled in the art to make and use the claimed methods.

Claim Rejections under 35 U.S.C. §112, 1st Paragraph, Written Description

Claims 45, 46, 48-57, 59-64, and 67-73 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention.

To provide adequate written description and evidence of possession of a claimed genus, the specification must provide sufficient distinguishing identifying

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characteristics of the genus. The factors to be considered include disclosure of complete or partial structure, physical and/or chemical properties, functional characteristics, structure/function correlation, methods of making the claimed product, or any combination thereof.

Claim 45 recites "a fragment of the CYK-4 protein comprising a GTPase activating protein domain". Claim 54 recites "a fragment of the CYK-4 protein comprises a domain that binds MKLP1 subfamily proteins". Claim 55 recites "a fragment of the MKLP1 protein subfamily member that comprises a domain that binds the CYK-4 protein or fragment of the CYK-4 protein". Claim 64 recites a fragment of the first CYK-4 protein and the second CYK-4 protein, each comprises a domain that mediates CYK-4 protein self –association. Claims 45, 54, and 64 recite variants of human CYK-4 (SEQ ID NO: 2) and murine CYK-4 (SEQ ID NO: 4) that are encoded by nucleic acids hybridizing under stringent conditions to a polynucleotide having a nucleotide sequence set forth in SEQ ID NO: 1 or SEQ ID NO: 3. Claims 48, 59, and 67 recite variants of human CYK-4 (SEQ ID NO: 2). The claims do not require that the fragment of CYK-4 protein or the variants of the CYK-4 protein possess any particular biological activity, nor any particular conserved structure, nor other disclosed distinguishing feature.

The instant disclosure of a human CYK-4 protein of SEQ ID NO: 2 encoded by a polynucleotide of SEQ ID NO: 1 and a murine CYK-4 protein of SEQ ID NO: 4 encoded by a polynucleotide of SEQ ID NO: 3 does not adequately support the

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scope of the claimed genus, which encompasses a substantial variety of subgenera including full-length genes. A description of a genus of cDNA may be achieved by means of a recitation of a representative number of cDNAs, defined by nucleotide sequence, falling within the scope of the genus, or of a recitation of structural features common to the genus, which features constitute a substantial portion of the genus. *Regents of the University of California v. Eli Lilly & Co.*, 119 F3d 1559, 1569, 43 USPQ2d 1398, 1406 (Fed. Cir. 1997). In the instant case, only a single species of human CYK-4 protein of SEQ ID NO: 2 and a single species of murine CYK-4 protein of SEQ ID NO: 4 are disclosed. They are not sufficient to support the genus of variants of human and murine CYK-4 proteins.

Due to the breadth of the genus of CYK-4 proteins and its fragments and lack of the definitive structural or functional features of the genus, one skilled in the art would not recognize from the disclosure that the applicant was in possession of the instantly claimed methods that recite the genus of CYK-4 proteins and its fragments.

Claim Rejections Under 35 U. S. C. §112, 2nd Paragraph

Claims 45, 46, 48-57, 59-64, 67-73 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

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45, 48, 54, 59, 64, and 67 are indefinite because they recite "...hybridizes under stringent conditions" without giving the specific conditions for hybridization in the claims. Since neither the art nor the specification provides an unambiguous definition for the term, the claims are indefinite. Claims 46, 49-53, 55-57, 60-63, and 68-73 are rejected as dependent claims.

Claim Objection —Minor Informality

The objection to claims 45, 46, 51-57, and 60-64, and 67-73 for reciting non-elected subject matter (murine CYK-4 of SEQ ID NO: 4) is maintained because Applicants have not amended the claims. Appropriate correction is required.

Claims 45, 54, 61, and 70-73 are objected to because of a typographic error: "fragment of the CYK-4 protein" should be "a fragment of the CYK-4 protein".

Conclusion

No claims are allowed.

Advisory Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ruixiang Li whose telephone number is (571) 272-0875. The examiner can normally be reached on Monday through Friday from 8:30 am to 5:00 pm. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa, can be reached on

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(571) 272-0829. The fax number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, please contact the Electronic Business Center (EBC) at the toll-free phone number 866-217-9197.



Ruixiang Li, Ph.D.
Examiner
August 4, 2005